PCT/EP00/07933

66

## Patent Claims

- 1. A method of treating a mammal or other living organism having a heart and a peripheral vascular system to achieve a heart load reduction, said organism having a pulse rate and a systolic pressure resulting from the action of the heart, the method comprising the steps of:
  - measuring the heart rhythm,
  - producing pressure pulsations in the peripheral vascular system by a non-invasive or invasive method in synchronization with the heart rhythm in the counterpulsation mode and
  - varying at least one parameter of an input system generating said pressure pulsations to produce an optimized reduction in at least one of said pulse rate and said systolic pressure and hereby a net reduction in said heart load, said heart load being a function of said pulse rate and said systolic pressure.
- 2. A method in accordance with claim 1, comprising the further step of adjusting the time at which stimulation is applied to said living organism by said input system to compensate for the reduction in pulse rate resulting from the treatment.
- 3. The method of either claim 1 or claim 2, wherein pressure pulsations are produced by subjecting the mammal to stimulating impulses of electrical energy at a position of the peripheral vascular system at which a smooth muscle or a skeletal muscle is present, excluding the heart and wherein the parameter varied is selected from the group comprising:

- the impulse delay before the start of counterpulsation, said impulse delay being the time difference between the Q-wave end of a QRS heart rhythm signal and the start of a train of stimulating impulses generating pressure pulsation,
- the train duration, i.e. the time between the start and end of a train of stimulating impulses within one QRS heart rhythm,
- the impulse width, i.e. the time between the start and end of each stimulating impulse of each said train,
- the frequency of the impulses forming a train of stimulating impulses generating pressure pulsation,
- the amplitude of stimulating impulses generating pressure pulsation,
- the impulse form, being the geometric form of the stimulating impulse resulting when an amplitude of the impulse is displayed over a full impulse duration,
- the impulse mode, being the relationship between positive and negative half cycles of each said electrical stimulating impulse.
- 4. A method in accordance with any one of the preceding claims, when used to treat a human being to achieve benefits in one or more fields selected from the following group:

promotion of fitness and wellness,
physical training for sport,
aesthetic medicine, including any kind of desired body shaping
and/or tissue changes, e.g. due to body fat burning (lipolysis), fluid
drainage and tissue and muscle growth and/or reduction as well as
associated skin changes,

curative medicine, including invasive and non-invasive methods, cosmic medicine.

5. A method in accordance with any one of the preceding claims, wherein said method is carried out in the field of curative medicine, or for the prevention of disease and/or rehabilitation in one of the following fields:

for anesthesiology, for example to reduce the risk of acute heart failure.

for cardiology, for example to remedy tachycardia, ischemic heart disease, cardiomyopathy, hypertension, heart failure, valvular pathology,

for angiology, for example for lymph-venous and arterial insufficiencies,

for orthopaedy and neurology, for example to remedy hypotrophy and atrophy of muscles,

for pain reduction including anti-pain TENS-treatment for any kind of pathology in the body support and motion system of a human being, for example for osteochondrosis,

for urology and proctology, for example for sphincter insufficiencies, for gynaecology and sexology, for example for the treatment of dilatatio vaginae, descendus uteri, adnexitis, amenorea, frigidity, for endocrinology, for example for adipositas partialis, hypomastia, for surgery, for example for diastasis musculi recti abdominis, decubiras,

for cosmic medicine, for example to preserve muscle tone of astronauts.

- A method of achieving a heart load reduction in a living body having a heart, such as a mammal and especially a human being by measuring the heart rhythm including the pulse rate and by producing pressure pulsations in the peripheral vascular system in synchronization with the heart rhythm in the counterpulsation mode to produce a reduction in at least one of the pulse rate and a systolic pressure and hereby a net reduction in the heart load being a function of the pulse rate and the systolic pressure.
- 7. A method in accordance with claim 6, wherein the step of producing pressure pulsations in the peripheral vascular system in synchronization with the heart rhythm in the counterpulsation mode is optimised to produce cardioresonance and hereby a maximum net reduction in the heart load.
- 8. Apparatus for treating a mammal or other living organism having a heart and a peripheral vascular system, said organism having a pulse rate and a systolic pressure resulting from the action of the heart, the apparatus comprising means for measuring the heart rhythm, means for producing pressure pulsations in the peripheral vascular system by a non-invasive or invasive method in synchronization with the heart rhythm in the counterpulsation mode and means for varying at least one parameter of such pressure pulsations to produce an optimised reduction in at least one of said pulse rate and said systolic pressure and hereby a net reduction in said heart load.

- Apparatus in accordance with claim 8, wherein said means for measuring the heart rhythm comprises an electrocardioscope and an associated set of electrodes.
- 10. Apparatus in accordance with claim 8, wherein said means for measuring the heart rhythm comprises at least one of a pulse sensor and an electrocardiograph.
- 11. Apparatus in accordance with claim 10, wherein said pulse sensor is located at any point of a patient's body for generating pulse signals in response to the patient's heart rhythm and adapted to transmit signals by wireless transmission.
- 12. Apparatus in accordance with claim 10 or 11, wherein said pulse sensor comprises a belt worn around a patient's chest and wherein at least one transmitter is provided for transmitting signals derived from said pulse sensor to said means for producing pressure pulsations.
- 13. Apparatus in accordance with any one of the preceding claims, wherein said means for producing pressure pulsations in the peripheral vascular system comprises a pulse generator for generating electrical signals and means for applying said electrical signals as stimulating signals to one or more skeletal or smooth muscles associated with said peripheral vascular system, whereby to produce said pressure pulsations in said peripheral vascular system.
- 14. Apparatus in accordance with claim 13, wherein said applying means comprises at least one neutral electrode and at least first and second active electrodes and wherein said electrical pulses are ap-

plied in a sequence to said first and second active electrodes, said at least one neutral electrode being connected to a neutral terminal of said pulse generator.

- 15. Apparatus in accordance with claim 14, wherein said sequence comprises a regularly repeating sequence.
- 16. Apparatus in accordance with claim 14, wherein said sequence comprises a random sequence.
- 17. Apparatus in accordance with any one of the preceding claims and further comprising a blood pressure measuring instrument for measuring a blood pressure of said mammal or other living organism.
- 18. Apparatus in accordance with claim 8, wherein said means for producing pressure pulsations in the peripheral vascular system comprises a pulse generator for generating electrical pulses and a pressure pulsation generator connected to receive said electrical pulses and generate pressure pulsations in response thereto and means for applying said pressure pulsations to a pressure pad adapted for mounting on a patient's body.
- 19. Apparatus in accordance with any one of the preceding claims and further comprising a safety means, said safety means being adapted to receive respective signals corresponding to said actual pulse rate and to one or more actual blood pressure values and to compare said actual pulse rate or said one or more blood pressure values with a respective preset values or values prevailing at the start of said treatment and to issue a warning signal or shut off said apparameters.

ratus when at least one of said actual pulse rate and one or more actual blood pressure values exceeds a respective predetermined limit or a prevailing value at the start of said treatment.

- 20. Apparatus in accordance with claim 8, wherein said pulse generator is adapted to produce trains of pulses, said pulses having a pulse repetition frequency, an amplitude, a pulse form, a pulse width and a pulse mode, and said trains having a duration and an pulse delay relative to a reference point of an ECG trace, and wherein means are provided for varying at least one of said pulse delay, said train duration, said pulse repetition frequency and said pulse amplitude.
- 21. Apparatus in accordance with claim 20, wherein said means for varying said pulse repetition frequency and said amplitude comprise manually adjustable means.
- 22. Apparatus in accordance with claim 20 or 21, wherein means are also provided for varying at least one said pulse form, said pulse width and said pulse mode.
- 23. Apparatus in accordance with claim 22, wherein said means for varying said pulse form, said pulse mode and said pulse width comprise manually adjustable means.
- 24. Apparatus in accordance with any one of the claims 20 to 23, wherein said pulse generator comprises a control unit and a memory for storing control settings of said control unit for the control of said pulse generator and wherein input means are provided permitting the inputting of control settings relating to at least said pulse

delay, said train duration, said pulse frequency and said pulse amplitude.

- 25. Apparatus in accordance with claim 24, wherein means are also provided for varying at least one of a form of each pulse, a width of each of said electrical pulses and a mode of said electrical pulses and wherein said input means are also provided for the inputting of further control settings relating to said pulse form, said pulse mode and said pulse width.
- 26. Apparatus in accordance with claim 24, wherein said control unit and said memory are adapted to permit storage of data relating to at least one of a patient's pulse rate, blood pressure and the stimulation applied over a period of time.
- 27. Apparatus in accordance with claim 26, wherein said apparatus includes output means permitting output of said stored data.
- 28. Apparatus in accordance with claim 8, wherein said apparatus comprises a display means for displaying at least one of a patient's pulse rate, an ECG trace for said patient, a blood pressure trace for said patient, actual settings of said pulse generator and electrical settings for stimulating pulses applied to said patient.
- 29. Apparatus in accordance with claim 8, wherein said pulse generator comprises means for deriving from said heart rhythm for each period of said heart rhythm a time corresponding to an end of each Twave of said heart rhythm and means for synchronizing the generation of pulses to coincide with the end of each said T-wave.



- 30. Apparatus in accordance with claim 8 in combination with a cardiostimulator, wherein said cardiostimulator defines said means for measuring the heart rhythm.
- 31. Apparatus in accordance with claim 30, wherein said means for producing pressure pulsations in the peripheral vascular system comprises a pulse generator integrated into said cardiostimulator.
- 32. Apparatus in accordance with claim 30 or 31, wherein said cardiostimulator is adapted to transmit a wireless signal corresponding to said heart rhythm and wherein said means for producing pressure pulsations in the peripheral vascular system is a muscle stimulator separate from said cardiostimulator and provided with a wireless receiver for receiving wireless signals transmitted by said cardiostimulator.
- 33. Apparatus in accordance with claim 30, wherein said cardiostimulator comprises a pacemaker, or a defibrillator, or a cardiomyostimulator.
- 34. Apparatus in accordance with any one of the preceding claims when incorporated into at least one article of clothing, e.g. a brassiere, or a pair of panties.
- 35. Apparatus in accordance with claim 8 when incorporated into a seat, said seat comprising one of a seat of a means of transport, an office chair, a chair for home use, a chair for clinic use and a chair for recreational purposes.

- 36. Apparatus in accordance with any one of the preceding claims, wherein said means for measuring the heart rhythm produces a heart rhythm signal, wherein means is provided for producing a systolic blood pressure signal, and wherein said means for producing pressure pulsations comprises a pulse generator having a controller, said controller being adapted to receive said heart rhythm signal and said systolic pressure signal and to control the pulse generator using a signal formed by combination of said heart rhythm signal and said systolic blood pressure signal.
- 37. Apparatus in accordance with claim 36, wherein means are provided for comparing said heart rhythm signal with a reference to form a heart rhythm factor, wherein means are provided for comparing said systolic blood pressure signal with a reference to form a systolic blood pressure factor, wherein means is provided for multiplying said hear rhythm factor and said systolic blood pressure factor to produce a resulting factor, and wherein said controller for said pulse generator is adapted to control said pulse generator to minimize said resulting factor.
- 38. Apparatus in accordance with any one of the preceding claims and further comprising a safety means, said safety means comprising means for monitoring at least one parameter of the means used for producing pressure pulsations in the peripheral vascular system and for comparing said parameter with at least one predetermined value limit and means for discontinuing the treatment or triggering an alarm should the monitored parameter exceed or fall short of said predetermined value limit.

- T



- 39. Apparatus in accordance with claim 38, wherein said predetermined value limit comprises at least one of a maximum or minimum value of a said parameter, a minimum or maximum gradient of a rate of change of the said parameter over time, a statistical deviation over time of a said parameter, or any combination of the foregoing.
- 40. Apparatus in accordance with any one of the preceding claims and comprising gating means for defining a window between successive R-R peaks within which sensed signals are inhibited from triggering stimulation signals, and wherein said gating means is preferably adjustable to vary the width and/or position of the window relative to the R-R cycle.
- 41. Apparatus in accordance with any one of the preceding claims and including timing means for triggering a stimulation signal after a delay following each R-peak corresponding to a minimum delay plus an offset delay, adaptive means for varying said offset delay in steps while monitoring, optionally over a plurality of heart beat cycles, one of the heart beat rhythm and the product of the heart beat rhythm and the systolic blood pressure and for identifying the offset delay which results in the lowest heart beat or lowest heart load and for subsequently operating the apparatus with this offset delay for the patient involved.
- 42. Apparatus in accordance with any one of the preceding claims in which the pressure pulsations in the peripheral vascular system are initiated by stimulation signals triggered in a time window lying within a range of 5 % of the R-R path before the end of the T-wave and 45 % of the R-R path after the end of the T-wave.